BlueCross BlueShield
Federal Employee Program
Blue Cross Blue Shield Association
750 9th St NW, Suite 900
Washington, D.C. 20001
1-800-624-5060
Fax 1-877-378-4727

5.21.241

Section:	Prescription Drugs	**Effective Date:**	July 1, 2025
Subsection:	Antineoplastic Agents	**Original Policy Date:**	March 21, 2025
Subject:	Romvimza	**Page:**	1 of 4

Last Review Date: June 12, 2025

Romvimza

Description

Romvimza (vimseltinib)

Background
Romvimza (vimseltinib) is a kinase inhibitor that inhibits colony-stimulating factor 1 receptor (CSF1R). In vitro, Romvimza inhibited CSF1R autophosphorylation, signaling induced by CSF1 ligand binding, and proliferation of cells expressing CSF1R (1).

Regulatory Status
FDA-approved indication: Romvimza is a kinase inhibitor indicated for the treatment of adult patients with symptomatic tenosynovial giant cell tumor (TGCT) for which surgical resection will potentially cause worsening functional limitation or severe morbidity (1).

Romvimza contains warnings regarding hepatotoxicity, allergic reactions to FD&C Yellow No.5 and No.6, and increased creatinine without affecting renal function. Liver tests, including AST, ALT, total bilirubin, direct bilirubin, ALP, and gamma-glutamyl transferase (GGT), should be monitored prior to initiation of Romvimza, twice a month for the first two months, and once every three months for the first year of therapy and as clinically indicated thereafter (1).

The recommended dosage of Romvimza is 30 mg orally taken twice weekly, with a minimum of 72 hours between doses, as directed on the blister package. Patients should be instructed to follow the schedule on the blister package and to take Romvimza on the same days each week (1).

Romvimza may cause fetal harm when administered to pregnant women. Females of reproductive potential should be advised to use effective contraception during treatment with Romvimza and for 1 month after the last dose (1).

The safety and effectiveness of Romvimza in pediatric patients less than 18 years of age have not been established (1).

Related policies
Turalio

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Romvimza may be considered **medically necessary** if the conditions indicated below are met.

Romvimza may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Symptomatic tenosynovial giant cell tumor (TGCT)

a. Surgical resection will potentially cause worsening functional limitation or severe morbidity

AND ALL of the following:

a. Prescriber agrees to monitor liver tests for hepatotoxicity during therapy and discontinue if necessary
b. Females of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Romvimza and for 1 month after the last dose

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Symptomatic tenosynovial giant cell tumor (TGCT)

AND ALL of the following:

a. **NO** disease progression or unacceptable toxicity
b. Prescriber agrees to monitor liver tests for hepatotoxicity during therapy and discontinue if necessary
c. Females of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Romvimza and for 1 month after the last dose

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity 24 capsules per 84 days

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Romvimza (vimseltinib) is a kinase inhibitor that targets colony stimulating factor 1 receptor (CSF1R). Romvimza is indicated in patients with symptomatic tenosynovial giant cell tumor (TGCT) for which surgical resection will potentially cause worsening functional limitation or severe morbidity. Liver tests should be monitored prior to initiation of treatment and during

treatment. The safety and effectiveness of Romvimza in pediatric patients less than 18 years of age have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Romvimza while maintaining optimal therapeutic outcomes.

References

1. Romvimza [package insert]. Waltham, MA: Deciphera Pharmaceuticals, LLC; February 2025.
2. NCCN Drugs & Biologics Compendium ® Vimseltinib 2025. National Comprehensive Cancer Network, Inc. Accessed on April 22, 2025.

Policy History

Date	Action
March 2025	Addition to PA
June 2025	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 12, 2025 and is effective on July 1, 2025.